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10/525,238	10/12/2005	Marco Frentsch	GULDE-0057	7138

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,238	FRENTSCH ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,10 and 13-15* is/are pending in the application.

4a) Of the above claim(s) *10, 13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/31/2008, has been entered.

Claim 1 has been amended.

Claim 15 has been added.

Claims 7-8 and 11-12 have been canceled previously.

Applicant's election with traverse of Group I, directed to methods of detecting the expression of CD154, including the election of species of "methods for detection", "anti-CD40 antibody", "extracellular detection", "vital cells" and "$CD4^+$ T cells", has been acknowledged in the previous Office Action.

Claims 1-6, 9 and 15 has been are under consideration as they read on the elected species.

Claims 10 and 13-14 have been withdrawn from consideration as being drawn to non-elected Groups or species.

2. The text of those sections of Title 35 USC not included in this Office Action can be found in a prior Office Action.
This Action will be in response to applicant's amendment, filed 12/31/2008.
The rejections of record can be found in previous Office Action, mailed 10/01/2008.

3. Priority.

As noted previously, receipt of the stamped WIPO foreign priority document EP 02090300.1, filed 08/23/2002, is acknowledged.

However, it does not appear that a certified English translation has not been provided in the instant application.

Therefore the effective priority date is the PCT/EP03/09354, filed 08/22/2003.

4. Applicant's Remarks, filed 12/31/2008 acknowledges the guidelines for the preferred layout for the specification of a utility application (see MPEP 608.01(a)) but chooses not to amend the specification accordingly.

5. Rebuttal to applicant's arguments with respect to the rejections under 35 USC 112, first and second paragraph, rejections.

Applicant's arguments filed 12/31/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

The present specification provides explicit guidance on the nature of CD154 molecules, including techniques and reagents that may be employed in the detection of the expression thereof. To this end, the specification for example, in the paragraph bridging pages 7 and 8, discloses that CD154 is expressed on CD4+ T cells and detection thereof may be made without undue experimentation. The specification further teaches that the art is replete with information on methods and reagents for the detection of CD154 on cell surface, as evidenced by the referenced articles by Berner et al. (2000) and Schonbeck et al. (2000). Moreover, insofar as methods for detecting changes in gene expression (i.e., mRNA levels) and gene-product expression levels (i.e., protein levels) are known in the art, a skilled worker can employ any routine technique, for example nucleic acid hybridization assays and/or antibody-based detection assays for practicing the claimed invention in its broadest possible scope. To this end, the present specification provides a detailed description of at least two embodiments, which may be utilized in the detection step. For example, at page 13 of the specification, a direct methodology for detection of CD 154 (e.g., FACS sorting or magnetic cell sorting) is described. See also, Example 3 of the specification wherein CD154-expressing T cells are detected and isolated using FACS. In page 14, ¶2, the specification provides an indirect method of detecting CD154 expression, wherein the in vivo effects of non-functional CD 154 expression is described. As such, the PTO's contentions regarding indefiniteness are without merit.

Under items 6 and 8 of the Office Action, it is alleged that CD40 is not expressed extracellularly in vital T-cells, and as such, the claimed subject matter is indefinite and/or non-enabled. These contentions are respectfully traversed. Since the Office Action has not presented evidence to support the allegations, the rejections based thereon are legally misplaced. In any event, Applicants have amended the claim to recite method steps that allow a skilled worker to practice the claimed invention in its broadest possible scope. Applicants' amendment of the claims is not to be construed as acquiescence to this or any other ground of rejection. Withdrawal of the rejection is respectfully requested.

Applicant is reminded that the rejections under 35 USC 112, first and second paragraphs, address applicant's applicant's election of Group I, directed to methods of detecting the expression of CD154, including the election of species of "methods for detection", "anti-CD40 antibody", "extracellular detection", "vital cells" and "$CD4^+$ T cells".

Applicant takes the curious position that the Office Action has not presented evidence to support the allegations that CD40 is not expressed extracellularly in T cells.

Applicant is invited to review their own disclosure, including pages 11-12 of the instant specification, as follows, which is consistent with the basic knowledge of the ordinary artisan for over a decade now that CD40 is not expressed extracellularly on T cells and CD154 is expressed on activated helper T cells.

CD40 is a membrane-bound glycoprotein of the TNF receptor gene family (tumor necrosis factor receptor gene family) and 45 to 50 kDa in size. It is developed by various hematopoietic cell types, but also by epithelial and endothelial cells, carcinomas, fibroblasts, and muscle cells. It can be bound by CD154 which accordingly is a member of the TNF gene family and likewise can be expressed by a large number of cells with highly varying functions. CD40 is expressed on various cells, such as B lymphocytes, dendritic cells, monocytes/macrophages, mast cells, hematopoietic stem/precursor cells (human), thymus epithelial cells (mouse), endothelial cells, fibroblasts (mouse), muscle cells (human) and/or carcinomas (human).

For example, CD154 is expressed on T lymphocytes, activated dendritic cells (human), monocytes, mast cells (human), basophilic/cosinophilic granulocytes (human), NK lymphocytes (mouse), fetal thymocytes (mouse) and/or B cells (human).

Furthermore, with respect to applicant's arguments that the rejections are legally misplaced, the rejections are deemed to be supported by the facts and legal principles

that applicant's claims fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention in absence of clear positive steps and ingredients to accomplish the claimed methods in the claims and in view of the elected species of anti-CD40 antibodies under 35 USC 112, second paragraph, and

there is insufficient direction and guidance as to how the disclosure enable how the skilled artisan would be able to detect the extracellular expression of CD154 on $CD4^+$ T cells with anti-CD40 antibodies under 35 USC 112, first paragraph,.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965).

Applicant's arguments have not been found persuasive.

6. Claims 1-6, 9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 and 9 are indefinite under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as they do not recite clear and definitive method steps and appear to be incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

For the third time, applicant is invited to review the claims carefully and consider amending the claims to recite positive steps and ingredients to accomplish the claimed methods.

For example, the recitation of "detecting the expression of CD154" in the absence of clear positive steps and ingredients to accomplish the claimed methods in the claims and in view of the elected species of anti-CD40 antibodies, wherein the elected methods are directed towards detecting the expression of the ligand of CD40, namely CD154/CD40 ligand/CD40L.

Also, it is noted that CD40 is not expressed extracellularly on vital $CD4^+$ T cells.

For example, the nature and parameters with respect to the recitation of "characterized" is that the nature or parameters of the claimed "characterization" is not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree or direction and, in turn, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention or the parameters by which to determine said metes and bounds.

Applicant's arguments, filed 12/31/2008, have been fully considered but have not been found convincing essentially for the reasons of record and addressed above in Section 4.

In contrast to applicant's arguments that the rejections are legally misplaced,
the rejection of record is deemed to be supported by the facts and legal principles that applicant's claims fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention in absence of clear positive steps and ingredients to accomplish the claimed methods in the claims and in view of the elected species of anti-CD40 antibodies under 35 USC 112, second paragraph.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965).

Applicant's arguments have not been found persuasive.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

7. Claims 1-6, 9 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments, filed 12/31/2008, have been fully considered but have not been found convincing essentially for the reasons of record and addressed above in Section 4.

In contrast to applicant's arguments that the rejection is legally misplaced,
the rejection of record is deemed to be supported by the facts and legal principles
there is insufficient direction and guidance as to how the disclosure enable how the skilled artisan would be able to detect the extracellular expression of CD154 on $CD4^+$ T cells with anti-CD40 antibodies under 35 USC 112, first paragraph,.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

With regards to the instant claims; their breadth, the state of the prior art, and the lack of guidance provided by the inventor, comprise the primary issues as regards the unpredictability of the claimed method.

As indicated above, applicant's election with traverse of Group I, directed to methods of detecting the expression of CD154, including the election of species of "methods for detection", "anti-CD40 antibody", "extracellular detection", "vital cells" and "$CD4^+$ T cells", has been acknowledged.

However, CD40 is not expressed extracellularly on vital $CD4^+$ T cell

The specification does not enable one of skill in the art, at the time the invention was made, to practice the claimed methods as currently claimed.

For example, in an effort to distinguish methods of detection from the prior art,
the instant specification describes methods of detecting antigen-specific T cells, which rely upon secretion inhibitors and endocytosis inhibitors (e.g., see page 14, paragraph 2 of the instant specification.
Here on page 14 of the specification, it is noted that the use of anti-CD40 antibodies affect CD40 in such a way that interaction with CD154 is no longer possible.

Example 3 on page 19 of the instant specification describes culturing T cells with anti-CD40 antibodies, however the detecting of CD154 is determined by anti-CD154 antibodies (i.e. anti-CD40L antibodies) antibodies and not by anti-CD40 antibodies.
It appears that the invention described in the specification as-filed relies upon stabilizing CD154 (CD40L) intracellularly in $CD4^+$ T cells with secretion inhibitors and endocytosis inhibitors as well as stabilizing CD154 with CD40-specific blocking antibodies and culture systems.

In the absence of essential ingredients and methods steps such as stabilizing CD154 (CD40L) intracellularly in $CD4^+$ T cells with secretion inhibitors and endocytosis inhibitors as well as stabilizing CD154 with CD40-specific blocking antibodies and culture systems,
there is insufficient direction and guidance as to how the disclosure enable how the skilled artisan would be able to detect the extracellular expression of CD154 on $CD4^+$ T cells with anti-CD40 antibodies.

The skilled artisan would not predict that extracellular expression of CD154 on $CD4^+$ T cells could be detected with anti-CD40 antibodies, given that anti-CD40 antibodies do not bind CD154, nor T cells.

Given the unpredictability of detecting the expression of an antigen in the absence of an agent or means to specifically detect said antigen, and lack of sufficient guidance and working examples in the present application, the experimentation left to those skilled in the art, would be unnecessarily, and improperly, extensive and undue.

For the third time, applicant is invited to recite clear and definitive method steps and ingredients to enable the claimed methods to detect CD154 extracellularly with anti-CD40 antibodies.

Applicant is cautioned against reading limitations into the claims and to point to a basis in the specification so as not to add any new matter.

8. As indicated above and previously, given the lack of enablement of applicant's elected species in detecting the extracellular expression of CD154 (CD40L) on $CD4^+$ T cells,
the election of species has been extended to the use of anti-CD154 (Anti-CD40L antibodies) to detect the extracellular expression of CD154 (CD40L) on $CD4^+$ T cells,

9. Claims 1-6, 9 and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Assenmacher et al. (WO 99/58977) (1449; #002) (see entire document).

Applicant's arguments, filed 12/31/2008, have been fully considered but have not been found convincing essentially for the reasons of record and herein.

Applicant argues the following.

While Assenmacher may disclose a method for the detection of antigen-specific T cells comprising employing CD40-specific antibodies, the cited reference is absolutely silent with respect to the detection of CD154, as recited in the present claims. More specifically, the reference is silent regarding the use of a CD154-specific antibody for the detection of said CD154. See, new claim 15. As such Assenmacher cannot anticipate the claims of the present application. It is required that for anticipation, the reference publication teach, either explicitly or inherently, all the elements of Applicants' claims. Absent such, there can be no anticipation.

In contrast to applicant's assertions about CD40-specific antibodies, the rejection is based upon CD40L-/CD154-specific antibodies.

In contrast to applicant's assertions about the use of a CD154-specific antibody, Assenmacher teaches CD40L (i.e., CD154) as a targeted marker for T cells (e.g., see page 27, paragraph).

Further, the teachings of Assenmacher et al. are replete with references to specific binding partners (see Disclosure of the Invention and Modes of for Carrying Out the Invention) and to antibodies as the specific binding partners (e.g., see page 17, paragraph 3 - page 18; page 27, paragraph 1; Cell Labeling on pages 29-36 and Cell Analysis and Cell Sorting on pages 36-39 and Diagnostic Methods for Detecting Antigen-Specific T cells on page 39-40).

As Assenmacher et al. teach that cell sorting and cell analysis methods were known in the art at the time the invention was made (e.g., see page 17, paragraph 2)

If applicant is arguing that Assenmacher et al. does not teach CD154 per se,
applicant is reminded that CD154 is simply an alternative designation for CD40L (CD40 ligand), wherein CD40L has been known as the counter-receptor for CD40 for over twenty (20) years.
Note, too, pages 7-8 of the instant specification describes CD40L in terms of CD154.
The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Assenmacher et al. teach detecting antigen-specific T cells based upon CD154-/ CD40L-specific antibodies (see entire document, including Effector Cell Populations on pages 26-29, Cell Analysis on pages 36-39, Diagnostic Methods for Detecting Antigen-Specific T Cells on pages 39—40 and Methods of Treatment Using Enriched Antigen-Specific T Cells on pages 40-42).

CD154 (CD40L) is expressed on activated $CD4^+$ T cells.

Given the broadest reasonable interpretation of the claims, including detecting $CD154^+$ ($CD40L^+$) T cells from patients with an inflammatory condition,
it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

10. Claims 1-6, 9 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Berner et al. (Ann Rheum Dis 59: 190-195, 2000) (1449; #003) (see entire document) and in further evidence by Darrell et al. (US 2003/0012781).

Applicant's arguments, filed 12/31/2008, have been fully considered but have not been found convincing essentially for the reasons of record and herein.

Applicant argues the following.

The rejection under of claims 1-6 and 9 under 102(b) as being anticipated by Berner (2000) and/or Bataglia (1999) is respectfully traversed. The Examiner contends that the references' disclosure of detection of antigen-specific T-cells from patients with rheumatoid arthritis and/or Crohn's disease meets all the elements of claims 1-6 and 9. See, page 8 of the Office Action. Applicants submit that the forgoing amendments render these rejections moot. More specifically, neither Berner nor Bataglia teach a method for isolating antigen-specific T cells comprising employing a CD40/CD154 system inhibitor which blocks or inhibits the interaction between CD40 and CD154 and detecting the expression of CD154. Additionally, the mere assertion that CD154 molecules are expressed in T-cells is insufficient for anticipation of the present claims. The Office Action has not established that CD154 molecules are in fact detected in these patients. As such these rejections are legally misplaced.

In response to applicant's assertions that Berner et al. did not teach an inhibitory anti-CD154/anti-CD40L antibody;
evidentiary evidence is provided herein to support that the anti-CD40L TRAP 1 antibody taught by Berner et al. (e.g., see Direct Immunofluorescence and FACS Analysis on page 191, column 2) can block CD40/CD40L interactions (see paragraph [0261] of Anderson et al.).

In contrast to applicant's unsupported assertions that the mere assertion that CD154 molecules are expressed in T cells is insufficient for anticipation in the instant claims,
applicant is invited to review the prior art and broadest reasonable interpretation and plain meaning of the claims.

For example, the title of Berner et al. is Increased Expression of CD40 Ligand (CD154) on $CD4^+$ T cells as a Marker of Disease Activity in Rheumatoid Arthritis.

Applicant fails to distinguish the prior art from anticipating the instant claims.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Berner et al. teach detecting antigen-specific T cells from patients with rheumatoid arthritis (see entire document, including Abstract and Conclusions on page 190; Methods, Results and Discussion).

CD154 (CD40L) is expressed on activated $CD4^+$ T cells.

Given the broadest reasonable interpretation of the claims, including detecting $CD154^+$ ($CD40L^+$) T cells from patients with an inflammatory condition,
it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

11. Claims 1-6, 9 and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Battaglia et al. (Am. J. Gastroenterology 94: 3279-3284, 1999) (see entire document).

Applicant's arguments, filed 12/31/2008, have been fully considered but have not been found convincing essentially for the reasons of record and herein.

Applicant argues the following.

The rejection under of claims 1-6 and 9 under ~ 102(b) as being anticipated by Berner (2000) and/or Batataglia (1999) is respectfully traversed. The Examiner contends that the references' disclosure of detection of antigen-specific T-cells from patients with rheumatoid arthritis and/or Crohn's disease meets all the elements of claims 1-6 and 9. See, page 8 of the Office Action. Applicants submit that the foregoing amendments render these rejections moot. More specifically, neither Berner nor Batataglia teach a method for isolating antigen-specific T cells comprising employing a CD40/CD 154 system inhibitor which blocks or inhibits the interaction between CD40 and CD154 and detecting the expression of CD154. Additionally, the mere assertion that CD154 molecules are expressed in T-cells is insufficient for anticipation of the present claims. The Office Action has not established that CD154 molecules are in fact detected in these patients. As such these rejections are legally misplaced.

In response to applicant's assertions that Battaglia et al. did not teach an inhibitory anti-CD154/anti-CD40L antibody;
Battaglia et al. teach rabbit anti-human antisera to human CD40L.

Given that prior art teaching of antisera to human CD40L, wherein antisera would comprise multiple epitopic specificities including those that would block CD40L:CD40 interactions,
the prior art antisera would have been more likely than not to have inhibitory properties encompassed by the claimed methods.

Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons.

The burden is on the applicant to establish a patentable distinction between the claimed and referenced anti-CD40L antibodies used in the claimed methods.

In contrast to applicant's unsupported assertions that the mere assertion that CD154 molecules are expressed in T cells is insufficient for anticipation in the instant claims,

applicant is invited to review the prior art and broadest reasonable interpretation and plain meaning of the claims.

For example, the title of Battaglia et al. is Expression of CD40 and Its Ligand CD40L, in Intestinal Lesions of Crohn's Disease.

In contrast to applicant's remarks, the prior art is not based upon mere assertions.

Applicant fails to distinguish the prior art from anticipating the instant claims.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Battaglia et al. teach detecting antigen-specific $CD4^+$ T cells from patients with Crohn's disease (see entire document, including Abstract, Results and Discussion).

CD154 (CD40L) is expressed on activated $CD4^+$ T cells.

Given the broadest reasonable interpretation of the claims, including detecting $CD154^+$ ($CD40L^+$) T cells from patients with an inflammatory condition,

it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
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Art Unit 1644
March 9, 2009